Reduction of Leg Pain by Oxiplex Gel After Lumbar Discectomy in Patients With Predominant Leg Pain and Elevated Levels of Lower Back Pain

A Prospective, Randomized, Blinded, Multicenter Clinical Study

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Study Design: A prospective, randomized, blinded, multicenter clinical study.

Objective: To evaluate carboxymethylcellulose/polyethylene oxide gel (Oxiplex) in improving clinical outcomes in subjects having predominant leg pain and elevated low back pain undergoing first-time lumbar discectomy for disk herniation.

Summary of Background Data: Clinical studies in the United States and Italy found that Oxiplex reduced leg pain after decompression surgery.

Methods: A total of 68 subjects with herniated lumbar disk were enrolled and randomized into treatment (surgery plus gel) or surgery-only control groups. A prospective statistical analysis assessed the effect of gel in the severe back pain subgroup (prespecified as greater than or equal to median baseline back pain of the population studied). All subjects except 2 controls lost to follow-up completed the study. Preoperative and postoperative visual analogue scale leg pain scores were analyzed and compared between groups at 60 days after surgery.

Results: There were no serious adverse events or neurological safety concerns reported in any patients. Gel-treated patients had statistically significantly lower visual analogue scale leg pain scores at study end compared with controls ($P = 0.0240$), representing a 21% additional reduction in leg pain compared with surgery alone in the severe baseline back pain subgroup ($P = 0.0240$). The proportion of subgroup patients experiencing zero leg pain at study end was significantly higher in the gel treatment group (60%) than in the control group (23%) ($P = 0.0411$).

Conclusions: The data from this study confirm and extend results of 2 previous studies in Italy and the United States that reported statistically significantly greater reductions in leg pain in gel-treated patients with severe preoperative low back pain compared with patients who only underwent decompression surgery.

Key Words: carboxymethylcellulose, polyethylene oxide, Oxiplex, MediShield, leg pain, sciatica, herniated disk, lumbar discectomy, adhesions

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Lumbar disk herniation (LDH) is a common indication for surgical intervention in spinal disease. The typical clinical presentation is a patient with severe unilateral radicular leg pain, whereas the amount of concomitant low back pain (LBP) varies from none to severe. Although the natural history of LDH has been actively studied, the relationship between the extent of disk degeneration and the severity of radicular pain and LBP remains unclear.[1–4] Recently, Kleinstück and colleagues reported that the level of preoperative LBP was a predictor of outcome after surgical decompression. They reported that the greater the amount of preoperative LBP relative to leg pain, the worse the postoperative outcome. As surgery for a herniated disk is primarily performed to alleviate radicular leg pain, the amount of concomitant LBP before surgery affects therapeutic decisions.[5,6]

MATERIALS AND METHODS

Oxiplex Gel (FzioMed Inc., San Luis Obispo, CA) (also known under the trade name, MediShield Anti-Adhesion Gel, distributed by Medtronic Inc., Memphis, TN) is a sterile, absorbable, viscoelastic gel comprised of carboxymethylcellulose and polyethylene oxide. Oxiplex is a device that was shown in preclinical[7] and clinical studies[8,9] to reduce fibrosis and tethering of adjacent tissues when applied to the surgical site and adjacent epidural space after laminectomy and laminotomy. It is placed around neural tissues after spine surgery to reduce adhesion formation and related symptoms such as pain and is approved in nearly 70 countries outside the United

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